REMARKS

This Amendment responds to the Office Action mailed February 11, 2009, in the above-identified application. Based on the foregoing amendments and the following comments, reconsideration and allowance of the application are respectfully requested.

Claims 1-34 are currently pending in the application. By this Amendment, claim 1 has been amended. The amendment finds clear support in the original application at least at page 5, lines 18-22 and in the drawings. No new matter has been added.

The Examiner has rejected claims 1-34 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claim limitation "in the absence of any device to close the oropharyngeal velum" is not supported by the original application. Applicants do not concur with the basis for the rejection. Nonetheless, in order to advance prosecution of the application, claim 1 has been amended to recite "in the absence of any device to seal the nasal cavities from the throat and mouth. This limitation finds support in the original application at least at page 5, lines 18-22 and in the drawings. In particular, the cited passage at page 5, lines 18-22 states:

> Without further measures, the main aerosol flow emerges from the other nostril in the patient's nose when the patient, as is usual with aerosol therapies for the paranasal sinuses, seals the nasal cavities from the throat and mouth by means of the soft palate.

Accordingly, the specification teaches that the patient seals the nasal cavities from the throat and mouth by means of the soft palate "without further measures." A device to seal the nasal cavities from the throat and mouth is referred to neither in this paragraph nor elsewhere in the application. Further, it is apparent from the drawings that no device to seal the nasal cavities from the throat and mouth is shown. Accordingly, amended claim 1 is in compliance with the written description requirement.

It is true that any negative limitation or exclusionary provision must have basis in the original disclosure, as provided by MPEP §2173.05(i). However, as discussed above, the negative limitation of amended claim 1 *does* have basis in the original disclosure. It is further noted that newly-added claim limitations must be supported in the specification through express, implicit, or inherent disclosure (MPEP §2163(B)). Thus, an express disclosure of the added claim limitation is not a requirement.

Based on the above discussion, it is submitted that amended claim 1 is in compliance with 35 U.S.C. §112, first paragraph, and withdrawal of the rejection is respectfully requested.

The Examiner has rejected claims 1, 3-6, 8-10, 13-16 and 18-34 under 35 U.S.C. §103(a) as unpatentable over Chantrel et al. (EP 0507707) in view of Djupesland (WO 00/51672). Claims 2, 11, 12 and 17 are rejected under 35 U.S.C. §103(a) as unpatentable over Chantrel et al. in view of Djupesland as applied to claim 1, further in view of Brugger (DE 3238149). Claim 7 is rejected under 35 U.S.C. §103(a) as unpatentable over Chantrel et al. in view of Djupesland as applied to claim 1, further in view of Landis et al. (US 5,687,715) The rejections are respectfully traversed for the following reasons.

Chantrel discloses a therapeutic nebulizer which is equipped with an inhaler nozzle to be applied to a patient's nose. A constant aerosol flow is guided through the patient's nose, and pressure fluctuations are superimposed which are intended to cause the aerosol particles/droplets in the main aerosol flow to pass through the nostril and into the paranasal sinuses. Chantrel fails to disclose a flow resistance device at the other of the alae of the patient's nose.

Djupesland discloses a device for delivering a substance to the nasal airway of a patient comprising, as a key feature, a closure unit for causing closure of the oropharyngeal velum of the patient. Djupesland also teaches a delivery unit for delivering a gas flow entraining a substance to one of the nostrils of the patient but at such driving pressure as to flow around the posterior

margin of the nasal septum and out of the other nostril of the patient. The delivery device also includes an outlet unit which includes an outlet for the gas flow and a flow resistor.

The Response to Arguments section of the Office Action suggests that the Examiner has disregarded the limitation relating to the absence of any device to close the oropharyngeal velum, based on the Examiner's assertion that the limitation fails to satisfy the written description requirement. As discussed above, claim 1 has been amended to recite the limitation "in the absence of any device to seal the nasal cavities from the throat and mouth", which limitation is clearly supported by the original disclosure.

Amended claim 1 therefore distinguishes over Chantrel and Djupesland. In particular, Chantrel does not disclose a flow resistance device configured to be placed at the other of the two alae of the user's nose. Djupesland discloses a device for delivering a substance to the nasal airway of a patient including, as a key feature, a closure unit for causing the closure of the oropharyngeal velum of the patient. Djupesland also teaches a delivery unit for delivering a gas flow entraining a substance to one of the nostrils of the patient, but at such driving pressure as to flow around the posterior margin of the nasal septum and out the other nostril of the patient. However, the key feature of the teaching of Djupesland is a device to close the oropharyngeal velum of the patient. This feature is described numerous times in the specification of Djupesland, as set forth in previous responses. According to Djupesland, a device to close the oropharyngeal velum is required. There is no teaching in Djupesland to rely on the effects of the outlet unit alone.

According to embodiments of the present invention, the flow resistance device provided at the other of the two alae of the user's nose is sufficient to achieve predictable deposition of the aerosol in the desired areas in the absence of any device to seal the nasal cavities from the throat and mouth. However, since the use of such a device is stressed repeatedly in Djupesland, Djupesland cannot be said to teach a therapeutic aerosol device as defined by amended claim 1.

In summary, Chantrel and Djupesland, taken individually or in combination, do not disclose or suggest a therapeutic aerosol device including *a flow resistance device configured to be placed at the other of the two alae of the user's nose, the flow resistance device, in the absence of any device to seal the nasal cavities from the throat and mouth, causing aerosol from the main aerosol flow having pressure fluctuations superimposed thereon to reach the paranasal sinuses of the user and to be deposited therein*, as required by amended claim 1. For at least these reasons, amended claim 1 is clearly and patentably distinguished over Chantrel in view of Djupesland, and withdrawal of the rejection is respectfully requested.

Claims 2-34 depend from claim 1 and are patentable over the cited references for at least the same reasons as claim 1.

Based upon the above discussion, claims 1-34 are in condition for allowance.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to

charge any deficiency or credit any overpayment in the fees filed, asserted to be filed, or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. P0777.70000US00.

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Respectfully submitted,

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